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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/288,719	04/09/1999	ROLAND KONTERMANN	26083/201	7814

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER

1632

DATE MAILED: 12/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/288,719

Applicant(s)
Kontermann et al.

Examiner
Anne Marie Wehbé

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 4, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 23-29, and 53 is/are pending in the application.
- 4a) Of the above, claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-18, 23-29, and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 21, 27 6) ☐ Other:

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DETAILED ACTION

Applicant's amendments and responses received on 3/11/02, 5/17/02, 6/26/02, and 10/4/02 have been entered. Claims 72, 78, and 83-86 have been canceled. Claims 1-18, 23, 25-29, and 53 are pending in the instant application. This application contains claim 5 drawn to an invention nonelected with traverse in Paper No.15 . A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 1-4, 6-18, 23, 25-29, and 53 are currently under examination in the instant application. The applicant is reminded that the following species have been elected for examination in the instant application: specificity A = the cell membrane of a target cell; specificity B = vector; the effector E = a prodrug activating enzyme; and the method of use = prophylaxis or treatment of cancer. It is noted however that the claims have not been amended to reflect the elected species and continue to read broadly on multiple species. As noted in the original office action, examination has been and continues to be limited to the elected species. An action on the merits follows.

Nucleotide and/or Amino acid Sequences

Applicant's supplemental sequence listing received on 10/4/02 has been entered. Please note that the CRF is technically good. This application is now in sequence compliance.

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Specification

Applicant's amendments to the specification on page 10 to insert portions of the document DE 196 49 645.4 which was improperly incorporated by reference have been entered. The declaration under 37 C.F.R. 1.132, as specified by *In Re Hawkins*, by the inventor Dr. Kontermann has also been entered. In view of the declaration by Dr. Kontermann, the office acknowledges that no new matter has been added by applicant's amendment to the specification.

Claim Rejections - 35 USC § 112

The rejection of claims 1, 23, 72, 78, and 85-86 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's cancellation of claims 72, 78, and 85-86 and in view of applicant's amendment to the specification on page 10.

The rejection of pending claims 1-4, 6-18, 23, 25-29, and 53 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is maintained in part. Applicant's arguments and the declaration under 37 C.F.R. 1.132 by Dr. Kontermann have been fully considered but

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have not been found persuasive in overcoming the remaining grounds of rejection for reasons of record as discussed in detail below.

The specification has been amended to recite particular antibodies which recognize determinants on target cells and target tumor cells, particular fusogenic peptides, and particular antibodies which recognize determinants in methylated DNA or on the envelope proteins of certain viruses. The declaration by Dr. Kontermann further provides evidence in the form of exhibits E and G that the nucleic acid sequences of the VH and VL domains of antibodies which recognize determinants on target cell membranes, and antibodies which recognize determinants on viral coat proteins or on DNA were available in the public domain at the time of filing. Based on these amendments and supporting evidence, the rejection for lack of written description has been withdrawn over VH and VL sequences which recognize determinants on target cell membranes, determinants on DNA, and determinants on viral coat proteins.

The applicant argues that the amendments to the specification provide sufficient description for the full scope of the claimed invention. However, the specification continues to fail to provide an adequate written description of a single chain VH-VL or VL-VH construct, or an antibody that binds to "vectors" consisting of cationic peptides, cationic proteins, cationic lipids, cationic polymers, or cationic porphyrins. Please note that claim 26 clearly indicates that the term "vector" encompasses these embodiments. The previously office action noted that the specification does not disclose or provide any written description for any VH-VL construct or antibody that binds to any type of vector, virus, or plasmid. The specification has been amended

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to incorporate sections of DE 196 49 645.4 which teach the use of antibodies against cell surface proteins of target cells such as tumor cells, and antibodies which recognize methylated DNA or viral coat proteins. Neither the DE 196 49 645.4 specification nor the instant specification provides any guidance or description regarding VH or VL sequences which bind to vectors which consist of cationic peptides, cationic proteins, cationic lipids, cationic polymers, or cationic porphyrins. The specification does not identify any particular antibodies which bind to any of these cationic “vectors”, or describe any physical or chemical characteristic of VH or VL nucleic acid or amino acid sequences which recognize these “vectors”. Thus, of the enormous number of possible VH and VL amino acid sequences and nucleic acid sequences encompassed by the claims, the specification lacks written description for the identity and the sequences of any antibody or VH-VL fragment which is capable of binding a cationic “vector” with sufficient affinity to be useful for making a diabody according to the instant invention. *Vas-Cath Inc. V. Mahurkar*, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of ‘written description’ inquiry, whatever is claimed” (see page 1117). By failing to identify or describe any antibody or VH or VL sequences specific for a viral or plasmid vector, the specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). Adequate written description requires more than a mere statement that an element is part of the invention. The sequence itself is required. Based on the applicant’s specification, the skilled

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artisan cannot envision the detailed chemical structure of the encompassed VH and VL sequences, therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. See *Fiers v. Revel*, 25 USPQ2d 1602 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

A handwritten signature in cursive script, appearing to read 'Anne M. Wehbé', positioned below the printed name and title.